IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	No. 20-md-2930-RGA
NOVARTIS PHARMACEUTICALS CORP., Plaintiff, v. CRYSTAL PHARMACEUTICAL (SUZHOU) CO., LTD., Defendant.	C.A. No. 21-1347-RGA C.A. No. 21-1797-RGA

MEMORANDUM OPINION

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ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me are Plaintiff's motions to dismiss the infringement claims and associated declaratory judgment counterclaims filed in civil actions 21-1347 and 21-1797 ("the ANDA suits"). (*See* C.A. No. 21-1347, D.I. 23; C.A. No. 21-1797, D.I. 22). I have considered the parties' briefing. (*See* C.A. No. 21-1347, D.I. 24, 28, 31; C.A. No. 21-1797, D.I. 23, 27, 30). For the reasons set forth below, Plaintiff's motions are GRANTED.

The briefing for these motions is identical. Thus, for convenience, I will consider them together and cite to the docket of C.A. No. 21-1347.

I. BACKGROUND

Plaintiff markets the drug product Entresto®. (*See* D.I. 24 at 1). Entresto® includes the drug compounds sacubitril and valsartan. (*See id.*). U.S. Patent Nos. 9,517,226 ("'226 Patent"), 9,937,143 ("'143 Patent"), and 11,135,192 ("'192 Patent") are listed in the FDA Orange Book for Entresto®. The '226, '143, and '192 patents' claims are directed to specific methods of using sacubitril and valsartan. (*See id.*).

Defendant submitted an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic version of Entresto® ("Defendant's ANDA product"). (*See id.* at 2). Thereafter, Defendant notified Plaintiff that it had filed certifications pursuant to 35 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications") for the '226, '143, and '192 patents. (*See id.* at 1-2). In response, Plaintiff filed the ANDA suits asserting that Defendant's ANDA product will infringe the '226, '143, and '192 patents under 35 U.S.C. § 271(e)(2). (*See id.* at 1, 6; D.I. 1 at ¶ 30). Defendant then filed counterclaims seeking declaratory judgment of non-infringement and invalidity for the '226, '143, and '192 patents. (*See* D.I. 24 at 1).

In May 2022, Defendant informed Plaintiff that it had converted its Paragraph IV certifications for the '226, '143, and '192 patents to a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) ("Section viii statement"). (*See id.* at 2 (citing *id.*, Ex. A)). The Section viii statement confirms that Defendant's ANDA product will not infringe any of the methods of use claimed in the '226, '143, and '192 patents. (*See id.*, Ex. A).

Plaintiff moves to dismiss without prejudice its claims in the ANDA suits under Rule 41(a)(2). Plaintiff also moves to dismiss Defendant's counterclaims in the ANDA suits under Rule 12(b)(6).

II. LEGAL STANDARD

A. Rule 41(a)(2)

Rule 41(a)(2) of the Federal Rules of Civil Procedure provides, "An action may be dismissed at the plaintiff's request only by court order, on terms that the court considers proper. If a defendant has pleaded a counterclaim before being served with the plaintiff's motion to dismiss, the action may be dismissed over the defendant's objection only if the counterclaim can remain pending for independent adjudication. Unless the order states otherwise, a dismissal under this paragraph (2) is without prejudice."

"[T]he grant or denial of voluntary dismissal without prejudice is a matter of judicial discretion...." *Ockert v. Union Barge Line Corp.*, 190 F.2d 303, 304 (3d Cir. 1951). "[A] court should grant a plaintiff's motion for voluntary dismissal unless the dismissal will result in substantial prejudice to the defendant." *Sanitec Indus., Inc. v. Sanitec Worldwide, Ltd.*, 2006 WL 890880, at *1 (D. Del. Apr. 3, 2006). "The mere prospect that a defendant will face a subsequent lawsuit is not legal prejudice." *Reach & Assocs. v. Dencer*, 2004 WL 253487, at *1 (D. Del. Feb. 9, 2004).

In determining whether legal prejudice will result from dismissal of a claim, "a court should consider 1) any excessive and duplicative expense of a second litigation; 2) the effort and expense incurred by a defendant in preparing for trial; 3) the extent to which the pending litigation has progressed; and 4) the claimant's diligence in moving to dismiss." *Reach & Assocs.*, 2004 WL 253487, at *1 (cleaned up).

B. Rule 12(b)(1)

Federal Rule of Civil Procedure 12(b)(1) permits the dismissal of a claim or an action for lack of subject matter jurisdiction. A Rule 12(b)(1) motion may be treated as either a facial or factual challenge to the court's subject matter jurisdiction. *See Davis v. Wells Fargo*, 824 F.3d 333, 346 (3d Cir. 2016). A facial attack contests the sufficiency of the pleadings, whereas a factual attack contests the sufficiency of jurisdictional facts. *See Lincoln Ben. Life Co. v. AEI Life, LLC*, 800 F.3d 99, 105 (3d Cir. 2015). When considering a facial attack, the court accepts the plaintiff's well-pleaded factual allegations as true and draws all reasonable inferences from those allegations in the plaintiff's favor. *See In re Horizon Healthcare Servs. Inc. Data Breach Litig.*, 846 F.3d 625, 633 (3d Cir. 2017). The party asserting subject matter jurisdiction bears "the burden of proof that jurisdiction does in fact exist." *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977).

In declaratory judgment actions, the plaintiff must show that "a case of actual controversy" exists to establish subject matter jurisdiction sufficient to maintain an action in federal court. 28 U.S.C. § 2201(a). The Supreme Court has held that a "case or controversy" exists when "the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

"The dispute must be definite and concrete, touching the legal relations of parties having adverse legal interests...." *Arris Grp., Inc. v. British Telecomm. PLC*, 639 F.3d 1368, 1373 (Fed. Cir. 2011) (cleaned up). A "subjective or speculative fear of future harm" does not suffice. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1335 (Fed. Cir. 2008).

C. Rule 12(b)(6)

Federal Rule of Civil Procedure 8(a)(2) requires a complainant to provide "a short and plain statement of the claim showing that the pleader is entitled to relief...." Rule 12(b)(6) allows the accused party to bring a motion to dismiss the claim for failing to meet this standard. A Rule 12(b)(6) motion may be granted only if, accepting the well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the complainant, a court concludes that those allegations "could not raise a claim of entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007).

The factual allegations do not have to be detailed, but they must provide more than labels, conclusions, or a "formulaic recitation" of the claim elements. *Id.* at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level ... on the assumption that all the allegations in the complaint are true (even if doubtful in fact)."). Moreover, there must be sufficient factual matter to state a facially plausible claim to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The facial plausibility standard is satisfied when the complaint's factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* ("Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." (cleaned up)).

III. DISCUSSION

Plaintiff states that "there is no longer an Article III case or controversy between [the parties] over [the '226, '143, and '192 patents]" because Defendant's "Section viii statement avers that [Defendant] is no longer seeking FDA approval for any [method of] use claimed by the ['226, '143, and '192] patents." (D.I. 24 at 1). Thus, Plaintiff argues that its claims should be dismissed without prejudice under Rule 41(a)(2) because (1) dismissal would not result in substantial prejudice to the Defendant, and (2) Defendant's counterclaims cannot remain pending for independent adjudication. (*See id.* at 3-7; *see also* Rule 41(a)(2)).

First, I find that dismissal of Plaintiff's claims would not result in substantial prejudice to the Defendant. The ANDA suits are at very early stages and the expenses already incurred by the Defendant are relatively minimal. *See Reach & Assocs.*, 2004 WL 253487, at *1 (considering "the effort and expense incurred by a defendant in preparing for trial"). Additionally, while Defendant argues that it will be prejudiced by the specter of Plaintiff re-asserting the '226, '143, and '192 patents (*see* D.I. 28 at 15-20), "[t]he mere prospect that a defendant will face a subsequent lawsuit is not legal prejudice." *Reach & Assocs.*, 2004 WL 253487, at *1. Further, Plaintiff was diligent in moving to dismiss after being notified that Defendant had converted its Paragraph IV certifications to a Section viii statement. *See Reach & Assocs.*, 2004 WL 253487, at *1 (considering "the claimant's diligence in moving to dismiss").

Second, I find that Defendant's counterclaims "[cannot] remain pending for independent adjudication." Fed. R. Civ. P. 41(a)(2). I find that this Court lacks subject matter jurisdiction over Defendant's counterclaims.

Defendant argues that this Court has subject matter jurisdiction over its counterclaims under 35 U.S.C. § 271(e)(2) and the Declaratory Judgment Act. (*See* D.I. 28 at 9-11). I disagree.

Having filed the Section viii statement, Defendant's ANDA no longer "seek[s] FDA approval for uses of [sacubitril and valsartan] covered by the ['226, '143, and '192] patents[.]" *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1379 (Fed. Cir. 2012); *see also id.* at 1374 n.2 (noting that some defendants "originally submitted Paragraph IV certifications ... but later amended their ANDAs to replace those certifications with Section viii statements"). Plaintiff can no longer "state a viable § 271(e)(2) claim" because "a patented method of using a drug can only be infringed under § 271(e)(2) by ... an ANDA that seeks approval to market the drug for that use." *Id.* at 1379. Therefore, this Court lacks subject matter jurisdiction over Defendant's counterclaims because Plaintiff's infringement claims are now without merit and of no "actual controversy." 28 U.S.C. § 2201(a). Indeed, Defendant no longer "remains under the threat of an infringement suit ... under [§ 271(e)(2)]" because it converted its Paragraph IV certifications to the Section viii statement. *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1341 (Fed. Cir. 2007).

In line with that conclusion, whether an ANDA applicant relied on a Paragraph IV certification is "dispositive" in determining whether they have a "justiciable declaratory judgment controversy." *Id.* at 1344 ("A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents...."). A Section viii statement "allows generic manufacturers to limit the scope of regulatory approval they seek—and thereby forego Paragraph IV certification and a § 271(e)(2)

infringement suit—by excluding patented indications from their ANDAs." *AstraZeneca Pharms.*, 669 F.3d at 1379.

Defendant also argues that it still faces an actual controversy because Plaintiff will not concede non-infringement and may re-file its infringement claims in the future. (*See* D.I. 28 at 11-20). I disagree. Defendant's concerns amount to no more than "subjective or speculative fear of future harm" that cannot justify subject matter jurisdiction. *Prasco*, 537 F.3d at 1335.

Thus, I find that this Court could not independently adjudicate Defendant's counterclaims because this Court would not have subject matter jurisdiction.

Having found that Defendant would not face substantial prejudice and that Defendant's counterclaims could not be independently adjudicated, I dismiss Plaintiff's claims without prejudice under Rule 41(a)(2). Further, having found that this Court lacks subject matter jurisdiction over Defendant's counterclaims, I will dismiss these counterclaims under Rule 12(b)(1).

Plaintiff also argues that Defendant's counterclaims should be dismissed under Rule 12(b)(6). (*See* D.I. 24 at 4-7).[1] Having found that Defendant's counterclaims should be dismissed under Rule 12(b)(1), I need not consider Plaintiff's Rule 12(b)(6) motions.

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[1] Plaintiff asserts, "[T]he Court retains subject matter jurisdiction over [Defendant's] counterclaims" and, thus, the question of whether the Defendant's counterclaims remain pending for independent adjudication depends on "whether a Section viii statement warrants dismissal [of Defendant's counterclaims] pursuant to [Rule] 12(b)(6)...." (D.I. 31 at 6). I disagree. Plaintiff's Rule 12(b)(6) motion repeatedly argues that dismissal is warranted because there is no longer an "Article III controversy." (*See generally* D.I. 24; D.I. 31). This is an argument for lack of jurisdiction. *See Ballentine v. U.S.*, 486 F.3d 806, 814 (2007) ("Under Article III, Section 2 of the Constitution, the jurisdiction of the federal courts is limited to actual cases or controversies.") (cleaned up); *see also id.* at 810 ("A motion to dismiss for want of standing is ... properly brought pursuant to Rule 12(b)(1), because standing is a jurisdictional matter."). Thus, I treat Plaintiff's Rule 12(b)(6) motion as a Rule 12(b)(1) motion for lack of subject matter jurisdiction.

IV. CONCLUSION

For the reasons stated above, Plaintiff's motions to dismiss are GRANTED.

An appropriate order will issue.